

REMARKS

Amendment to the Claims

Claims 1, 4-6, 9-14, 17-29, 31-33 and 39 were under examination as of the issuance of the Office Action of January 13, 2005. Claims 18-24 were previously withdrawn in response to a Restriction Requirement issued January 29, 2002. Claims 1, 4-6, 9-14, 17, 25-29, 31-33 and 39 stand rejected. In the Amendment to the Claims spanning pages 2 to 5 of this paper, claims 1, 4-6, 25 and 33 are currently amended and claims 18-24 and 27 are canceled without prejudice. Accordingly, upon entry of this amendment, claims 1, 4-6, 9-14, 17, 25, 26, 28, 29, 31-33 and 39 will remain pending in this application.

Claims 1 and 4 are amended to specify that the nucleic acid molecule encodes a polypeptide having 6-phosphogluconolactonase activity. Support for these amendments can be found throughout the specification, for example, on the first page of Table 1. Claims 5, 6, 25 and 33 have been amended to correct formalities and to clarify the subject matter of the claims as suggested by the Examiner.

Claims 18-24 and 27 have been canceled without prejudice to their inclusion in a subsequently filed application.

No new matter has been added by these claim amendments. Applicants reserve the right to pursue the claims as originally filed in one or more further applications.

Priority

Applicants acknowledge that the instant claims are granted the priority date of June 23, 2000, the filing date of the instant application. Additionally, Applicants note that certified copies of the foreign German patent applications will be filed upon issuance of a patent, upon which Applicants request grant of foreign priority.

Objections to Claim 27

In the Office Action, claim 27 was objected to under 37 C.F.R. § 1.75 as being in improper multiple dependent form and for “containing ‘the step of transfecting’ wherein the remainder of the claims is drawn to transformed bacteria.” In the interest

of expediting examination and in no way conceding the validity of the Examiner's assertion, Applicants have canceled claim 27, without prejudice, thereby rendering this objection moot.

Objection to Claim 33

In the Office Action, claim 33 was objected to for containing improper Markush language. In the interest of expediting examination and in accordance with the Examiner's suggestion, Applicants have amended claim 33, without prejudice, to recite "wherein the amino acid is selected from the group consisting of..." Accordingly, Applicants respectfully request withdrawal of this objection of claim 33.

Withdrawn Claim Rejections Under 35 U.S.C. § 112

Applicants gratefully acknowledge the Examiner's withdrawal of the following rejections:

- a) rejection of claims 5 and 9 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "naturally occurring;"
- b) rejection of claims 13-14 under 35 U.S.C. § 112, second paragraph, as being indefinite because claim 12 uses the term "transfected" while claims 13-14 are drawn to transformed bacteria;
- c) rejection of claim 17 under 35 U.S.C. § 112, second paragraph, as being indefinite for use of the term "produced" polypeptide; and
- d) rejection of claims 5 and 9 under 35 U.S.C. § 112, first paragraph, written description, as being directed to allelic variants.

Rejection of Claims 1 and 5 Under 35 U.S.C. § 112, Second Paragraph

The Examiner has rejected claims 1 and 5 under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In particular, the Examiner is of the opinion that

[i]n Claim 1, the phrase "a complement thereof" (emphasis added) is unclear because only one complement of SEQ ID NO:1 is known and the article --a-- indicates more than one...

Similarly in Claim 5, the phrase “the complement of a nucleic acid molecule consisting of SEQ ID NO:1” (emphasis added) is unclear for the same reasons.

In the interest of expediting examination and in accordance with the Examiner’s suggestion, Applicants have amended claims 1 and 5, without prejudice, to recite “the complement thereof” and “the complement of the nucleic acid molecule consisting of SEQ ID NO:1,” respectively. In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1 and 5 under 35 U.S.C. § 112, second paragraph.

Rejection of Claim 6 Under 35 U.S.C. § 112, Second Paragraph

The Examiner has rejected claim 6 under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In particular, the Examiner is of the opinion that “it is unclear which ‘complement’ is intended.”

In the interest of expediting examination and in accordance with the Examiner’s suggestion, Applicants have amended claim 6, without prejudice, to recite “comprising (a) a nucleotide sequence which has at least 90% identity with the nucleotide sequence of SEQ ID NO:1, wherein said nucleic acid molecule encodes a polypeptide having 6-phosphogluconolactonase activity, or (b) the complement of (a)”. In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 6 under 35 U.S.C. § 112, second paragraph.

Rejection of Claims 5, 6 and 9 Under 35 U.S.C. § 112, First Paragraph

The Examiner has rejected claims 5, 6, 9, 17 and 39 under 35 U.S.C. § 112, first paragraph as not being sufficiently enabled. In particular, the Examiner is of the opinion that

...it is the present position that 90% and/or 95% identity to SEQ ID NO:1 is not enabled. Applicant argues that the few sequences of 6-phosphogluconolactonases in the art (as IDS filed November 1, 2004) enable the claimed invention; this is not the case. These other disclosures of 6-phosphogluconolactonases “do not enable one of skill in the art to make all, or a relevant portion of, the polynucleotides within the scope of the claims because the ability to find a phosphogluconolactonase gene, which is structurally related to SEQ ID NO:1, is not equivalent to the ability to make a

6-phosphogluconolactonase gene as required by the statute (i.e., “make and use”) (see previous Office Action). NO alignment showing conserved residues is shown in the prior art.”

Applicants traverse the foregoing rejection as it pertains to claim 6, and claims depending therefrom, for the following reasons. Applicants would like to bring to the Examiner’s attention Example 14 of the *Revised Interim Written Description Guidelines Training Materials*. This example provides that a claim directed to variants of a protein having SEQ ID NO:3 “that are at least 95% identical to SEQ ID NO:3 and catalyze the reaction of A→B” with an accompanying specification that discloses a single species falling within the claimed genus, satisfies the requirements of 35 U.S.C. §112, first paragraph for written description. The rationale behind the foregoing conclusion, as presented by the *Written Description Guidelines*, is that “[t]he single species disclosed is representative of the genus because all members have at least 95% structural identity with the reference compound and because of the presence of an assay which Applicant provided for identifying all of the at least 95% identical variants of SEQ ID NO:3 which are capable of the specified catalytic activity.” The Guidelines also provide that “[t]he procedures for making variants of SEQ ID NO:3 are conventional in the art and an assay is described which will identify other proteins having the claimed catalytic activity. Moreover, procedures for making variants of SEQ ID NO:3 which have 95% identity to SEQ ID NO:3 and retain its activity are conventional in the art.”

Similarly, in the present case, claim 6, and claims depending therefrom, are directed to nucleic acid molecules that are at least 90% or 95% identical to SEQ ID NO:1, wherein the nucleic acid molecule encodes a polypeptide having 6-phosphogluconolactonase activity. The indication in Example 14 of the *Written Description Guidelines* that the production of polypeptides which contain a 5% variation from a specific sequence is routine in the art can be equated with the production of nucleic acid molecules which contain a 5% variation from a specific sequence. Furthermore, Applicants have disclosed in the instant specification assays for identifying all of the at least 90% or 95% identical nucleic acid sequences of SEQ ID NO:1 that encode for a polypeptide having 6-phosphogluconolactonase activity

(see, for example, Examples 4-8 on page 51, line 29 through page 56, line 28 of the specification).

In view of the above, Applicants respectfully submit that an ordinarily skilled artisan reading the foregoing teachings in Applicants' specification would have been able to practice the claimed invention using only routine experimentation. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

Moreover, Applicants traverse the foregoing rejection as it pertains to claim 5, and claims depending therefrom. Applicants note that although the Examiner has rejected claim 5, the Examiner's arguments in support of the rejection are specific to the claims directed to sequence identity (*i.e.*, claim 6). Despite the aforementioned lack of supporting arguments, Applicants would like to make the following remarks of record. Claim 5 is sufficiently enabled by the teachings in Applicants' specification. Specifically, at page 28, line 29 to page 29, line 6, Applicants teach how one of skill in the art would be able to generate these nucleic acid molecules and test the encoded polypeptide for activity. Indeed, Applicants have defined particular hybridization conditions such that it would be well within the ability of a skilled artisan to prepare an isolated nucleic acid molecule of claim 5.

Based on the foregoing teachings in Applicants' specification, as well as the general knowledge in the art at the time of the claimed invention, one of skill in the art would be able to make and use the claimed invention using only routine experimentation. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 5, 6, 9, 17 and 39 under 35 U.S.C. § 112, first paragraph.

Rejection of Claims 1-5, 7, 10, 13 and 15 Under 35 U.S.C. § 102(e)

The Examiner has rejected claims 1, 4-6, 9-14, 17, 25-29, 31-33 under 35 U.S.C. §102(e) as being anticipated by Dunican *et al.* (USPN 6,797,509) (hereinafter referred to as "Dunican"). In particular, the Examiner is of the opinion that

Dunican *et al.* teach a 6995 base pair DNA sequence comprising SEQ ID NO:1 from 6093-6920... Dunican *et al.* also teach using said DNA sequence in the production of amino acids, in particular lysine, threonine, and tryptophan, after having been transformed into C.

glutamicum, for example (see abstract, column 1, lines 10-14, and column 3, lines 65-67). The Examiner notes that such teachings are supported in the priority document 60/142915 on July 9, 1999 by Dunican *et al.*

Applicants traverse the foregoing rejection for the following reasons. Claims 1 and 4-6, as amended, are directed to nucleic acid molecules comprising SEQ ID NO:1 and encoding a polypeptide having 6-phosphogluconolactonase activity or nucleic acid molecules encoding a polypeptide having 6-phosphogluconolactonase.

For a prior art reference to anticipate, in terms of 35 U.S.C. § 102, a claimed invention, the prior art must teach each and every element of the claimed invention.

Lewmar Marine v. Barient, 827 F.2d 744, 3 USPQ2d 1766 (Fed. Cir. 1987).

Applicants respectfully submit that Dunican fails to teach all the elements of the claims, as amended. Specifically, Dunican fails to teach or suggest nucleic acid molecules having the 6-phosphogluconolactonase activity required by independent claims 1 and 4-6 as amended. Indeed, Dunican fails to even characterize their sequence, particularly nucleotides 6193-6898, as containing an open reading frame encoding a polypeptide having a 6-phosphogluconolactonase activity as identified in the present application. Not only does Dunican fail to disclose an isolated nucleic acid molecule encoding a polypeptide having a 6-phosphogluconolactonase activity, but they also identify their disclosed nucleic acid molecule of SEQ ID NO:1 as having a transaldolase activity. Accordingly, Dunican fails to teach each and every element of the claimed invention.

In view of all of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of the pending claims under 35 U.S.C. § 102(e).

CONCLUSION

In view of the foregoing remarks, reconsideration of the rejections and allowance of all pending claims is respectfully requested. If there are any remaining issues or if the Examiner believes that a telephone conversation with Applicants' Attorney would be helpful in expediting prosecution of this application, the Examiner is invited to call the undersigned at (617) 227-7400.

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Respectfully submitted,

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